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Trade and Agricultural Biotechnology:
Policy Inferences for India**

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Biosafety Protocol, International Trade and Agricultural Biotechnology: Policy Inferences for India

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Abstract: The growing development in and possibly greater diffusion of biotechnology products have further accentuated the intensity of trade restrictions on the entry of these goods in countries like EU, Japan and South Korea. While India initiates the various measures to implement the Biosafety protocol it is essential that specific trade policy responses are thought of on priority. This would be important for effective implementation of other Multilateral Environmental Agreements (MEAs) as well. In this context apart from other measures certain institutional initiatives need to be launched; for instance regional and sub-regional cooperation, focus on development of necessary skills for quarantine and other agencies, precautionary measures without affecting the trade facilitation measures. At the regional level, initiatives like Biosafety Clearing House and risk assessment mechanism should be effectively put in place. In order to facilitate this the policy specific scientific responses for risk assessment and risk management may also be finalised at the earliest possible.

Key Words: Biosafety, Trade, Agricultural Biotechnology and Regional Cooperation

I. Introduction

With the growing commercial availability of biotechnology products, the trade in genetically modified products has increasingly become a subject of major dispute among various national governments. There are two different groups of countries with different approaches towards GM products. Some countries have adopted the principle of ‘sound science’ as a basis for

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facilitating trade in GM products, while some others promote the use of 'precaution' in decision-making when there is no absolute scientific certainty and thereby restricting the trade in GM products. The US, Canada and Argentina represent the former group while EU, Japan and South Korea are from the later group. This debate has triggered a sort of fear among several developing countries, which are exporting agricultural commodities to EU and other countries as the export prospects of their agricultural products become very bleak.

This was evident in the Conference of Parties to the Convention on Biological Diversity (CBD), serving as the meeting of the Parties to the Cartagena Protocol on Biosafety (COP/MOP-2) held in Montreal, Canada from May 30 to June 3, 2005, wherein parties failed to reach an agreement regarding the documentation requirements for shipments of living modified organisms meant for food, feed and processing (LMO-FFPs). Notwithstanding this dilemma, the COP/MOP 2 made progress on less controversial issues such as risk assessment and management, capacity building, public participation and awareness. However, issues that have strong implications for developing countries, such as socio-economic considerations and liability and redressal did not yield notable outcomes, with some countries even expressing caution over the use of the former as a trade barrier.¹ The deadlock and slow progress on critical issues of biosafety could seriously affect both the exporters as well as the importers of the GM crops. Almost two years after the Protocol came into force some of its provisions and proposed mechanisms are still contentious and ambiguous despite the fact that the Protocol is a legally binding international agreement for the trans-boundary movement of genetically modified organisms (GMOs).

These developments pose a serious policy challenge for India in particular, as efforts are on through agricultural biotechnology to come out from productivity stagnation in the post HVY phase. The private investment in this technology is growing and so are the government allocations.² However, there is a need to work out a fine tunnel policy to adequately balance Indian interests in international trade vis-a-vis. Indian commitments at the Cartagena Biosafety Protocol with squeezing the policy space for adoption of new technologies.

This paper is an attempt to explore various contours of this intricate debate. The second section analyses the main feature of the Cartagena Protocol. The third section provides an overview of the current status of agricultural biotechnology in India. The fourth section analyses the current biosafety scenario in India. While identifying certain shortcomings in the regulation it also provides suggestions that would help to enhance its efficiency. The last section provides the conclusions and policy recommendations.

II. Biosafety Protocol: Main Features and Current State of Play

The *Rio Earth Summit* (1992) signified the international commitment for sustainable global development. The Summit adopted various instruments for translating the principles of *Agenda 21* into reality including the *CBD*.³ The Convention establishes three main goals, viz. the conservation of biological diversity, the sustainable use of its components, and the fair and equitable sharing of the benefits from the use of genetic resources. As part of its mandate given in Article 19, paragraph 3, the *CBD* established an *Open-ended Ad Hoc Working Group on Biosafety* to develop a draft protocol on biosafety. The work at this group eventually led to the adoption of the *Cartagena Protocol on Biosafety* in the year 2000 and entered into force on 11 September 2003. There are 124 national governments which have signed the Protocol.⁴ After five years of intense negotiations governments finalized a legally binding agreement for protecting the environment from risks posed by the transboundary transport of living modified organisms (LMOs)⁵ using modern biotechnology.

Under the Cartagena Protocol on Biosafety, governments will signal whether or not they are willing to accept imports of agricultural commodities that include LMOs by communicating their decision to the world community via an Internet-based Biosafety Clearing House. In addition, shipments of these commodities that may contain LMOs are to be clearly labelled. LMOs include various food crops that have been genetically modified for greater productivity or nutritional value, or for resistance to pests or diseases. Common examples include tomatoes, grains, cassava, corn, and soybeans. Together these agricultural LMOs form the basis of a multi billion-dollar global industry. Pharmaceuticals derived using LMOs form the basis of an

even larger industry (although pharmaceuticals are not covered by this agreement). Stricter 'Advanced Informed Agreement' (AIA) procedures will apply to seeds, live fish, and other LMOs that are to be intentionally introduced into the environment (Article 7.2). In these cases, the exporter must provide detailed information to each importing country in advance of the first shipment, and the importer must then authorize the shipment. The aim is to ensure that recipient countries have both the opportunity and the capacity to assess risks involving the products of modern biotechnology. Moreover, the information should also include the modification introduced, the technique used and the resulting characteristics of the LMO, the regulatory status of the LMO in the country of export and the contact details of the importer and the exporter. The notification has to be accompanied by a risk assessment report. Another important feature of the Protocol emanates from Preamble and Articles 1, 10 and 11. This is "precautionary approach". This means that if there is a scientific uncertainty about the impact of genetic manipulation on biodiversity and human health then the importer country may enforce restriction on imports and this flexibility would remain till importer on its own arrives on scientific certainty about implications.

One of the most contentious issues that negotiators had to resolve involved the relationship between the Protocol and other international agreements, notably those under the WTO. While environmental agreements are premised on the precautionary principle (which states that potentially dangerous activities can be restricted or prohibited even before they can be scientifically proven to cause serious damage), decisions under trade law require "sufficient scientific evidence". Under the agreement, the Protocol and the WTO are to be mutually supportive; at the same time, the Protocol is not to affect the rights and obligations of governments under any existing international agreements. The SPS Agreement also acknowledges the precautionary principle through the SPS and in fact this is a well established principle in many other multilateral agreements on environment. Some of the key features of the protocol are being discussed herewith. There is a great debate in the literature on whether the expressions like precautionary principle or precautionary approach is used.⁶ US has officially negated existence of any such principle while EU in its various reports has been

arguing in favour of acceptance of this principle. In India, some of the other MEAs signed by the MoEF do accept existence of the principle. There are more than 200 MEAs out of which about 20 contain trade restrictive measures. Reference to precaution has been outlined in more than ten MEAs and regional environmental agreements and the language ranges from the soft to hard approach. Apart from these MEAs, there are about 14 interpretations of precaution in treaties and other declarations. The most common reference to precaution is enshrined into the Principle 15 of the Rio Declaration on Environment and Development, 1992. The precautionary principle continues to provide the basis of several other global environmental agreements. The principle is now a familiar component of domestic policies relating to the environment, and recommends that measures based on the precautionary approach should be (1) proportional to the chosen level of protection (implicitly, if the country's level of preparedness is high then, through appropriate risk management practices some of the potential harms could be reduced); (2) non discriminatory in their application; (3) consistent with similar measures already taken; (4) based on an examination of the potential benefits and cost of action or lack of action (including where appropriate and feasible, an economic cost benefit analysis); (5) subject to review, in light of new scientific data and (6) capable of producing scientific evidence necessary for a more comprehensive risk assessment.

Precautionary Principle/Approach

The precautionary approach, in general, aims to deal with the hypothetical risks, when the link between the cause and the harm is yet to be determined. It is based on the concept of taking action against potential risks which are not, or not yet identifiable. This is particularly relevant to GMOs since it is an evolving technology whose dangers are yet to be proven. It has been argued that for the purpose of environmental protection, the precautionary approach may be implemented when there are two main factors involved – 1) When there is a presence of risk or potential hazard, and 2) Where there is a lack of scientific certainty on the extent of the potential damage or effect on human health and the environment from an action, product, or process.⁷ It is a matter of difficult policy choice how to approach the precautionary principle (See Box 1).

Box 1: Various Ways of Approaching Precautionary Principle

Implementating the precautionary principle is likely to be easier in those countries, where it is feasible to make political decisions in the face of scientific uncertainty, without having to quantify effects; less judicial review of decisions; and less influence by economic interests. Differences in the way the United States and European countries might implement precaution are illustrated in the controversy over phthalates in PVC children's toys.

The Danish government banned phthalates in toys designed for children under three without calculating risks quantitatively. Instead, they based the decision on qualitative considerations:

- Exposure was occurring;
- Phthalates are toxic to laboratory animals;
- Children may be uniquely susceptible to toxic substance;
- Alternative were readily available.

By contrast, the US government prepared a quantitative risk assessment of the impacts of phthalate exposure to children and found that the risk was very low. Nevertheless, officials called for a voluntary removal of phthalates based on residual uncertainties. And several major toy companies quickly complied, touting their decision, which was no doubt based on market pressures and the threat of litigation, as a voluntary move to protect the safety of children.

The key question in the implementation of the Precautionary regime is that what structures and changes will be required to implement the precautionary principle? The first change should be the questions asked by decision-makers. Instead of asking, "What level of risk is safe or acceptable?" they must ask "What alternatives exist to a potentially harmful activity?" and "Can harm be prevented?" These questions will shift the focus from analysis to careful planning.

Source: Tickner, Joel and Nancy Myers (2000).

importing Parties should make their decisions in accordance with the risk assessments that are carried out in a 'scientifically sound manner' and that the exporting country should bear the financial responsibilities for risk assessment if the county of import so requires. Apart from assessing the potential risks of GMOs on a case-by-case basis, it is important to take into account the technique by which the organism is altered and also the geo-ecological environment in which they are released.⁸

The use of precautionary approach in the Protocol is likely to create a conflict with the World Trade Organization (WTO) agreements, which also has an indirect reference to the same. The CPB and the WTO, within the realm of environment and trade, are governed by often-divergent sets of principles and objectives. The main difference in the reference to precautionary approach between the CPB and the SPS is its explicit adoption in the former and its indirect reference or precautionary use of language in the SPS (Article 5.7).⁹ The SPS, in its reference to the precautionary principle, states that where scientific evidence is insufficient, a member can adopt a measure *provisionally* based on pertinent information, but they should obtain scientific evidence '*within a reasonable period of time*'. Meanwhile, the CPB recognizes a country's right to take precaution in the face of uncertainty.

This SPS Article is a contentious topic among groups with divergent interests. The European Commission and Consumer groups oppose the use of the word 'provisionally' in the SPS since it suggests the imposition of time limits. On the other hand, business groups considered the Article to be a lacuna that allows trade restriction without a scientific basis.¹⁰ The SPS allows trade barriers to be imposed provided there is a scientific justification through risk assessment.¹¹ The SPS also somewhat assumes that there is sufficient scientific evidence to form a decision. However, the argument in the case of GMOs under the CPB is that there is yet no sufficient information to determine the health impacts, thus rendering it difficult to conduct a scientific risk assessment.

The interesting case is of the EU ban in 1989 of meat and meat products import derived from animals treated with bovine growth hormone from the US "to protect its consumers from potential effects". The US contested the

ban citing lack of scientific evidence that the use of bovine growth hormone poses threat to human health. The WTO dispute resolution in 1998 that ruled the ban violated the SPS Agreement, was a protectionist measure and not an environmental initiative. The Appellate Body's decision on the Hormones Case had maintained that the imposition of regulations by the governments on the basis of 'theoretical' risk that underlies scientific uncertainty is not sufficient. This decision is perhaps a reflection of the hesitance of the WTO in implementing the precautionary principle.¹² The ruling can also be seen as an endorsement of the strength of the WTO over the CPB despite the latter's declaration in its preamble that the Protocol is not subordinate to any other international agreement. In case of almost all the MEAs, the dispute settlement is considered to be institutionally weak, thus lacking provisions as in the WTO to ensure its implementation. Moreover, a non-party to the MEA cannot challenge trade measures before the agreement.¹³ So, if a trade dispute arises, the WTO is likely to take the role of the arbitrator.

Liability and Redress

Since there is no established international liability regime for Genetically Modified crops there is a major challenge of linking GMOs to liability and redress issues. The entry into force of the Biosafety Protocol has signalled the start of a process that should lead to the development of international rules on liability and redress.¹⁴ CoP-MoP 1 and CoP-MoP 2 had an extensive discussion about this issue.¹⁵ Nevertheless, the types of issues surfacing in the context of biotechnology are not completely new and a number of responses have been developed at the national and international levels.

The development of a liability and redress regime for GMOs raises a number of questions that need to be addressed separately. This is linked to the fact that the introduction of GMOs into the environment raises novel issues which have not necessarily been examined in the context of previous negotiations over environmental liability regimes. Thus, one of the main operative principles of the Biosafety Protocol is the precautionary principle and this principle influences the whole legal regime to put in place something which needs to be reflected in the liability and redress regime. Further, what constitutes damage arising as a result of the introduction of GMOs

into the environment cannot be limited to definitions usually adopted to-date. Some of the novel elements that need to be incorporated include the question of socio-economic damage and patent liability.

At the domestic level, the development of a liability regime is influenced by several factors. Firstly, the existing legal regime exhibits the same limitations as the international law regime insofar as it does not include any biotechnology-specific liability regime. Secondly, the adoption of a liability and redress regime at the international level necessitates the adoption of a related liability and redress regime at the national level since the rules adopted under the Biosafety Protocol will not address all relevant domestic situations. Thirdly, the existing compensation and liability regime is insufficient to deal with some of the specificities of genetically modified organisms.

In several countries a number of treaties introducing specific liability regimes have been adopted in the case of hazardous activities such as hazardous waste disposal, nuclear energy and oil pollution damage¹⁶, but they tend to provide broadly similar schemes. Firstly, they usually adopt the principle of strict liability in recognition of the need to channel liability to the promoter or operator of the dangerous activity. In certain cases, the strict liability framework is supplemented by a fault-based liability for individuals contributing to causing the damage through negligence or premeditation. Some treaties provide a possibility for the entity to which the liability is channelled to have recourse against other actors, while some deny this option to the operator such as in the case of nuclear energy. Liability is also nearly always limited in time even though this limit can extend to several decades. The amount that can be obtained is also nearly always finite. With regard to the damages taken into account, damage to the environment through the consideration of damages to persons and property as well as economic interests are usually been taken into account. There has, however, been a move towards the inclusion of other elements, such as the costs of preventive measures and the costs of restoration of a degraded environment. However, even newer treaties do not usually take into account compensation for non-economic components of the environment where measures to restore the environment cannot be taken.

One regional instrument with some noteworthy features is the *Lugano Convention* which recognises among dangerous activities the production, culturing, handling, storage, use, destruction, disposal, release or any other operation dealing with GMOs. The *Convention* also defines damage which proposes to include not only impairment of the environment – limited to the costs of measures of reinstatement actually to be undertaken – but also the costs of preventive measures and any loss or damage caused by preventive measures.

Since existing international frameworks in the case of modern biotechnology is limited, insights on the possible shape of an international and a domestic liability and redress regime can be gained by examining some of the existing biotechnology-specific liability regimes such as the Organization of African Unity's Model Law on Safety in Biotechnology, and the Switzerland's Gene Technology Act. These rules may provide some pointers in the development of a liability regime for India with country specific requirements. Some of the relevant policy options are enumerated in Box 2. There are several national liability regimes in countries such as submissions from Australia, Austria, Belgium, Canada, the Czech Republic, Denmark, Equatorial Guinea, the European Union, Fiji, Finland, Germany, Norway, Romania, Slovenia, Switzerland, the United States of America and Viet Nam.¹⁷ However, here we are focusing on OAU Law and Swiss Gene Technology Law only.

OAU Law on Safety in Biotechnology

The Organization of African Unity (OAU) draft African Model Law on Safety in Biotechnology, finalized in May 2001, was endorsed by the OAU Assembly of Heads of State and Government in July 2003. At its 74th Ordinary Session convened in Lusaka, Zambia the OAU Council of Ministers endorsed the Model Law. The Council furthermore urged its member states to use the Model Law to draft their own national legal instruments in order to create a systematic and Africa-wide biosafety regime to regulate the movement, transport, and import into Africa of GMOs.

The OAU and the Ethiopian Environmental Protection Authority took the initiative to develop a draft African Model Law on Safety in

Biotechnology to serve as a basis for formulating national laws and/or achieving similarity among national laws. The idea was that OAU would facilitate the development of a mechanism to implement liability regime in the region. The law at the outset itself recognizes that the modern biotechnology might have much promise for the improvement of human well-being but at the same time suggests to be guarded against its potential adverse effects on human health, biological diversity and in general towards the environment.

According to this law a person who imports, arranges transit, makes contained use of, releases or places on the market a genetically modified organism or a product of a genetically modified organism shall be strictly liable for any harm caused by such a genetically modified organism or a product of a genetically modified organism. The law categorically suggests that the harm caused by this action would be fully compensated. In the case of harm to the environment or biological diversity, compensation shall include the costs of reinstatement, rehabilitation or clean-up measures which actually are being incurred and, where applicable, the costs of preventive measures. In the case of harm to human health, compensation shall include all costs and expenses incurred in seeking and obtaining the necessary and appropriate medical treatment and compensation for any disability suffered, for diminished quality of life, and for all costs and expenses incurred in reinstating, as far as possible, the quality of life enjoyed by the person before the harm was suffered.

The Model Law is not legally binding, does not have any legal relationship with any other biosafety laws in Africa or elsewhere, and does not require any formal process by individual Member States of the AU for its adoption.

Swiss Gene Technology Law

Switzerland has gone through an intensive discussion on some aspects of the biosafety. There the Swiss Gene Technology Law envisages coexistence in the agricultural cultivation systems with genetically modified plants and non-genetically modified plants. However, it also argues for ensuring the consumer's freedom of choice.¹⁸ Though in Switzerland legal threshold values were defined because, it is impossible to rule out mixing completely

no matter how much care is taken. They specify the percentage of genetically modified material which can be included in food and animal feeds without having to label them as genetically modified. In line with the EU, a threshold value of 0.9 per cent is set in Switzerland. This value is embodied in both the Foodstuffs Ordinance and the Animal Feed Ordinance. The Gene Technology Law cites no limiting values.

Swiss Gene Technology Act defines the harm to the environment by the costs of necessary and appropriate measures taken to restore destroyed or harmed components of the environment, or to replace them with components of equal value. Swiss Gene Technology Act provides elaborated rules of challenging liability. In principle, the owner of an installation, that

Box 2: Policy Options for Liability Regime for Modern Biotechnology

- The development of a liability and redress regime for modern biotechnology can be linked in part to existing environmental liability and redress treaties developed over the past couple of decades since a number of basic issues are similar.
- Further work needs to be carried out in certain areas that have not been adequately covered earlier or that are specific to modern biotechnology. These include the question of socio-economic damage and the necessity to address the potential clash between the environmental, health and socio-economic liability of the entity introducing GMOs into the environment.
- There is also a need to assess the patent liability linked to the fact that most GMOs introduced on the market are protected by patents or other intellectual property rights.
- The issue of goods in transit needs to be considered. It is in general not possible to 'recall' a genetically modified organism introduced into the environment. Measures taken only at the national level or the international level will be insufficient to guarantee compliance with biosafety norms and principles.
- Two options can be proposed to remedy this situation. Either a major legislative effort is undertaken to develop an India-specific liability regime or a regime based on existing laws, as discussed earlier, need to be introduced to ensure that existing regulatory gaps are filled.

Source: Cullet (2005).

uses LMOs is liable for harm that may be caused during handling due to modification of the genetic material. Specifically, if the harm was caused by bringing LMOs on to the market for use as aids to agriculture or forestry, the following operators shall be liable:

- The producer who first placed these organisms on the market;
- If the organisms have been imported into the country;
- The producer who first placed them on the market abroad and the importer are jointly and severally liable;
- The owner of a company or installation that imports such organisms for its own use is jointly and severally liable with the producer; and
- Recourse to persons who have handled such organisms improperly, or have otherwise contributed to the creation or worsening of the harm, is reserved.

III. Agricultural Biotechnology in India

The agricultural biotechnology industry has expanded in India in a major way. The number of agricultural firms engaged in the agricultural biotechnology sector has gone up from 85 in 2001 to 132 in 2003 (see Table 1). There were in total 176 biotechnology firms in India, of which almost 48 per cent were agriculture based companies, 24 per cent with an interest in health related medical activities and 28 per cent were with varied interests, including in environmental biotechnology. In 2003, the number of biotechnology firms was 401, with healthcare firms showing the largest increase, overtaking the number of agricultural biotechnology companies. The share of healthcare sector firms increased from 24 per cent to 35 per cent while that of agriculture based firms declined from 48 to 33 per cent.

Some important private institutions in the non-profit sphere have come up to link biotechnology with sustainable development. For example the M. S. Swaminathan Research Foundation (MSSRF) of Chennai, has taken up important initiatives in terms of bridging the gap between technology development, its commercialization and ultimately its diffusion. One of the leading projects MSSRF launched in early 1990s was the establishment of Biovillages in India and China. The Biovillage approach aims at covering principles of ecological sustainability and economic profitability with equity. This project actively promoted interaction between society, industry and

Table 1: Sectoral breakdown of biotechnology firms in India

	2001		2003	
	Number	Share in total (%)	Number	Share in total (%)
Agriculture	85	48.3	132	32.9
Healthcare	43	24.4	142	35.4
Environment	4	2.3	16	4.0
Industrial biotechnology	—	—	—	42
10.5				
Others	44	25.0	69	17.2
Total	176	100	401	100

Source: Chaturvedi (2005).

R&D institutions. Some of the firms such as Indo-American Hybrid Seeds Company, Bangalore and R&D institutions such as Tamil Nadu Agricultural University were prominent partners. This project boosted the demand for biofertilisers in southern Indian villages.

Similarly, other institutions and NGOs like Foundation for Biotechnology Education and Awareness, Bangalore; Gene Campaign, New Delhi and Navdanya, New Delhi are also actively working in the area of biotechnology apart from many others.

It is interesting to find that in the year 2003 more than half of the biotechnology firms were small, with less than 50 employees, while firms with 150 employees or more accounted for one quarter of the total (see Table 2). This was again a sharp rise over 2001 in which only 107 were small firms. It is also interesting to see that number of small firms has grown much sharper in the healthcare sector where several start-up firms have emerged. In both the sectors medium size firms have grown almost at the similar pace. The healthcare sector is also the one in which number of large firms has also grown by 88 per cent which signifies rapid entry of transnational corporations in the sector. The small firms in this sector are largely the Contract Research Organisations (CROs).

In the agriculture sector, there are very few firms in the business of transgenics. They are largely firms dealing with biofertilizers, biopesticides

Table 2. Number of biotechnology firms by size and sector (2001 and 2003)

	Total		Agriculture		Environment		Healthcare		Industrial/Biotech		Others	
	2001	2003	2001	2003	2001	2003	2001	2003	2001	2003	2001	2003
Small firms (<51 employees)	107	248	63	87	4	9	10	74	—	39	30	39
Medium firms (51-150 employees)	24	78	10	26	—	1	8	21	—	15	6	15
Large firms (>150 employees)	45	102	12	19	—	6	25	47	—	15	8	15
Total no. of firms	176	401	85	132	4	16	43	142	—	42	44	69

Source: Chaturvedi (2005).

Table 3: Number of employees in the biotechnology industry in India

	2001		2003	
	Total	%	Total	%
Agriculture	15029	20.31	32623	20.3
Healthcare	28520	38.53	85600	53.2
Environment	66	0.1	6136	3.8
Industrial Biotechnology	—	—	14514	9.0
Others	16905	22.8	22026	13.7
Total	74011	100.0	160899	100.0

Source: Chaturvedi (2005).

and tissue culture. There is also sizeable growth in firms dealing with sectors like environment and industrial biotechnology. In the environment sector, firms are dealing with waste management and business related to biosensors. The activity are wide in the industrial biotechnology sector. It includes areas like enzyme production, herbal extraction, genomics and proteomics tools, etc.

In these firms the employment scenario has also become very important and India has long term potential to contribute in the biotechnology related services sector. In 2001, the healthcare sector enterprises provided employment to about 39 per cent of total jobs created by biotechnology (Table 3), which increased to 53 per cent of the total by 2003. This sharp rise in the health sector over-shadowed the increase in employment in other sectors as well. For instance, in agriculture the growth was 12 per cent, while the increase in the environment sector was even sharper. The number has gone up from 66 in 2001 to 6 136 in 2003. The concentration of technical manpower in the health sector has increased in a major way from 2001 to 2003. Similarly, in the agriculture sector the number of technical people have gone up from 5217 to 12 206. The industrial biotechnology sector has in any case started at a high point of 3 335, which is almost 9 per cent of total technical jobs created by all the sectors together.

IV. The Protocol and Indian Biosafety Policy

With India emerging as a major agricultural exporter and importer, the need to regulate GMOs is imperative. There are several rules/ guidelines issued by different ministries that govern various aspects of GMOs, but so far none of them have covered trade. These rules include the *Environment Protection Act, (EPA) 1986*, released by the Ministry of Environment and Forests (MoEF), the *Recombinant DNA Safety Guidelines, 1990*, and the subsequent *Revised Guidelines for Research in Transgenic Plants, 1998*, prepared by the Department of Biotechnology (DBT), and the department's recently released *National Biotechnology Development Strategy (Draft)*. There are some proposed policies as well, such as the *Seed Act, 2004* by the Ministry of Agriculture; the *Draft Food Safety and Standards Bill, 2005* by the Ministry of Food Processing Industries; the *Draft Plant Quarantine Order, 2003* by the Ministry of Agriculture and Cooperation, and the

Prevention of Food Adulteration Act and Rules by the Ministry of Health.

These multiple rules and regulations underline the complexities involved in biosafety as it cuts across ministries and agencies and do not merely govern environmental issues. Most of these regulations deal with GMOs in seclusion without referring to a common agency or secretariat to deal with the risks that are associated with the organism. In order to evolve an efficient domestic policy that is also in line with the Protocol, the entire gamut of ministries and stakeholders that participate in international agreements such as the WTO, especially the TRIPs, TBT and the SPS can be taken into confidence and these multiple rules can be harmonized to evolve a national strategy on biosafety. The idea of setting up of the National Biotechnology Regulatory Authority (NBRA), as recommended by the M. S. Swaminathan Task Force, may be assessed from the perspective of bridging this regulatory gap.¹⁹ This may help to address the prevailing ambiguity about the GM trade in India. There is an apprehension that GM grains and processed food are already being imported into the country *albeit* non-existent trade regulations. The challenge, therefore, is to address the current policy dilemmas while ensuring the growth of the biotechnology sector.

The Indian biosafety policy should take into account the Protocol which maintains that an exporting country should notify the importing parties of the first LMOs meant for intentional introduction into the environment, such as fish or seeds. The importer reserves the right of approval for the LMO shipment in accordance with scientifically sound risk assessments before agreeing to its import through a process termed as the AIA. LMOs intended for food, feed and processing (FFPs), which constitute a bulk of traded goods worldwide, are exempted from the AIA. Instead, they are subjected to a milder and simpler form of stipulation where the exporter notifies the biosafety clearing-house (BCH), an information exchange mechanism on the internet. LMOs meant for contained use, pharmaceuticals, and those passing via a third party country are also excluded. In India, these mechanisms are still to be worked out, as the BCH programme is being developed and implemented by MoEF. The exemption of FFPs from the AIA does not necessarily entail any less stringent export procedure if the national

regulations of the importing country require the FFPs to be subjected to labelling and identification requirements as mandated by the Protocol.²⁰ Failure to reach a resolution on the issue of documentation in the COP/MOP 2 only reinforces the urgency of a domestic policy on GMOs.

V. Concluding Remarks and Policy Recommendations

Biotechnology is now seen as an instrument for addressing food security concerns and thus an important component in the poverty reduction strategy that ultimately contributes to fulfilling the Millennium Development Goals. There is an optimistic approach towards biotechnology from the private sector and the budgetary allocations have also increased. In India, the total number of biotechnology firms in 2005 is 401 out of which 32 per cent are from the agricultural sector. There are more than 20 firms in the agricultural sector that are involved in the development of transgenic crops.²¹ These developments are in part an outcome of the active public policy in the promotion of biotechnology and the R&D strength of public sector institutions. The removal of quantitative restrictions in 2001 also led to greater agricultural trade liberalization which opened up the Indian import market for agriculture goods. However, the regulatory agencies and their guidelines are yet to gear up to respond to these dynamic developments. On the one hand, there is a growing indigenous strength in the area of agricultural biotechnology and burgeoning agricultural imports, and on the other hand are the challenges that emanate from the ambiguities in the national biosafety guidelines.

The precautionary approach in the current framework of biosafety in India would be unlike those used in other countries, particularly the developed nations, which are differently placed. In developing countries, including India, biotechnology products are also seen as instruments for achieving food security and addressing the prevalent productivity stagnation in the green revolution varieties. At the same time, these countries often express concern that the lack of regulation in their countries could encourage the indiscriminate use and testing of GMOs produced in developed countries. It is important that India balances the concerns related to precautionary approach with the need of industry and socio-economic needs of farmers apart from addressing the obligations under the SPS and the TBT agreements of WTO.

In the case of liability there is a need to develop an internationally accepted assessment procedure. This may be supplemented by the domestic liability regime, efforts for which in any case are on even in case of other agricultural commodities. The Commission for Agriculture Cost and Prices (CACP) of India has already developed guidelines and schemes in context of agricultural crops which may at best be modified to accommodate Bt specific nuances. The National Biosafety Guidelines may also draw upon from the existing biotechnology related liability regimes in other countries keeping in mind the country specific concerns that may not be addressed by these regimes. There are three key elements to be taken into account when formulating a domestic L&R regime for GMOs – environmental damage, socio-economic aspects and patent liability, a relatively new element that has not been incorporated in most country liability regimes.

In terms of socio-economic analysis an international common methodology to assess the socio-economic impacts would help to address the policy limitations at the domestic level. In this regard, data on numerous socio-economic indicators can be developed and used as a guide for the government to facilitate technology diffusion in a more effective manner. Other critical points may be considered such as accessibility of the technology across different land holdings and whether the technology necessitates any prior knowledge; whether the price of seeds or the safe adoption measures prescribed lead to exclusion of certain classes of farmers from adopting GM technology; wage difference between the GM growers and the non-GM growers and degree of contact with the LMO and health impacts on the farmer and the cattle. It also needs to assess how biotechnology impacts on labour dynamics in the country.²² Similarly, the impact of GM crops on small and marginal farmers need to be analysed.

Some additional policy measures have to be taken to make biosafety guidelines a comprehensive and dynamic policy mechanism rather than just a tool for regulation.

a. Need for Regional and Sub-regional Cooperation

Biotechnology has emerged as one of the important links in the regional and sub-regional cooperation programme. In the Asian context, BIMSTEC,

Asian Cooperation Dialogue (ACD) and Indian Ocean Rim Cooperation are some of the groupings in which different South Asian countries are participating and there biotechnology has been identified as a priority area for cooperation. In this regard, international support by various agencies should be explored so as to overcome the scientific uncertainty and methods for traceability.

b. Cooperation in Human Resource Development

It is important to realize that some of the developing countries especially in Indian sub-continent are facing constraints on the front of trained manpower in the second generation biotechnology. In this regard, the GEF supported biosafety programmes should be expanded to cover adequate training programmes for capacity building in the relevant ministries and agencies. Human resource development is also important for facilitating technology transfer and adoption when it comes to international collaboration.

c. Documentation and Trade Facilitation

The impasse at the COP/MOP 2 on the subject of documentation reflects the need to strengthen the Indian biosafety guideline. Studies need to be conducted to tabularize the national experiences in handling, transport and packaging and identification of LMOs at the level of different countries. Then it may be considered as to what can be done from the trade facilitation perspective. The process of documentation is expected to be rigorous and also involves high costs which needs to be assessed.

On the issue of traceability and threshold value too, there is no consensus worldwide due to the inherent difference in sampling and standardization methods. The Indian guidelines should look into the scientific level of harmfulness of the product. But for this, appropriate infrastructure should be in place, such as effective detection and cost involved in segregating and labelling and its ultimate impact on consumers. This may also help in deciding whether documents of LMO shipment should include a commercial invoice, an annex to a commercial invoice, or a stand-alone document and also what should be the content of the invoice has to be clearly outlined by the national guidelines.

d. Capacity of Quarantine Agency

The quarantine agency is an important focal point for the effective enforcement of biosafety regulation in India. The Plant Quarantine (PQ) Order, 2003, released by the Ministry of Agriculture reflects the vital role played by the quarantine agencies regarding the import of GMOs. At the same time, it also highlights the risks involved if quarantine inspectors are not well equipped. Most of the quarantine stations in the country are technically weak in dealing with GMO imports.²³ The Order refers to the Ministry of Environment and Forest's (MoEF) Environment Protection Act, 1986, and Rules 1989 for bulk shipment of GMOs.²⁴ Since the PQ Order is still a draft, there is space for amendments such as the incorporation of the phytosanitary requirements for GM agricultural commodities that is at par with international standards. It could also include a comprehensive notification regarding the regulation of imports of germplasm/GMOs/transgenic plant material, including bulk import of GM food grains.²⁵

e. Biosafety Clearing House

The biosafety clearing-house is one of the core components of the CPB. It is a storehouse of information on GMOs and other biosafety issues, thereby assisting countries in the implementation of the protocol. Users can readily access or contribute relevant biosafety-related information and this would assist governments to make informed decisions regarding the importation or release of LMOs. However, India's contribution to the BCH website is certainly minimal and as such information on biosafety issues related to India is limited.²⁶ It is possible to develop a national or regional BCH by harnessing the talent in the Information Technology industry in India and subsequently providing technical support to other regional partners.

f. Risk Assessment and Management

In India, since risk assessment and risk management (RARM) of GMOs is a relatively new research field, existing facilities are not sufficiently equipped to completely meet the requirements of the Protocol. So the current infrastructure needs to be improved and upgraded.²⁷ Training courses can be conducted for professionals to identify the potential gene flows and its effect on non-target species. The first step in RARM would be to collect the fundamental information of GMOs followed by the identification of

any novel genotypic and phenotypic characteristics associated with it, which may have adverse effects on the biological diversity. Field capacity can be developed which monitors the gene flow between the introduced LMOs and semi domestic and wild relatives.²⁸

To develop an effective governance of biotechnology and to minimize duplication of effort in this regard, it is important to harmonise the different policies and regulations formulated by different ministries. It has been suggested that a single authority or an inter-ministerial board address the differences in opinion on policymaking.²⁹ There is also a need to develop expertise in legal, and socio-economic issues that focus on analysis of the linkages between the protocol and other international agreements, measures related to biosafety and their trade impacts, cost benefit analysis, bioethics, legal drafting and policy analysis.³⁰ Ultimately an efficient and credible regulation should be accessible and transparent to incorporate the interest of the public in decision making.

Endnotes

- ¹ Earth Negotiations Bulletin (2005).
- ² Chaturvedi, 2005.
- ³ Agenda 21 is a comprehensive plan of action to be taken globally, nationally and locally by organizations of the United Nations System, Governments, and Major Groups in every area in which human impacts on the environment. This was adopted by more than 178 Governments at the United Nations Conference on Environment and Development (UNCED) held in Rio de Janeiro, Brazil, 3 to 14 June 1992.
- ⁴ Monday, July 25, 2005.
- ⁵ This international protocol uses the term LMO rather than GMO. It is assumed that this is a more precise term. LMO is defined as, “any living organism that possess a novel combination of genetic material obtained through the use of modern biotechnology” (Article 3 (g)).
- ⁶ Graham (2002); Wiener & Rogers (2002); and Desai (1997).
- ⁷ OECD (2002).
- ⁸ Volker, Lehmann (2002).
- ⁹ Charnovitz, Steve (2002).
- ¹⁰ *ibid*
- ¹¹ Article 2.2 of the SPS Agreement of the WTO maintains that SPS measure be applied ‘only to the extent necessary to protect human, animal or plant life or health, is based on scientific principles and is not maintained without sufficient scientific evidence.’
- ¹² Volker, Lehmann (2002).
- ¹³ Eric Neumayer (2002).

- ¹⁴ The mandate for this is found in Article 27 of the Protocol which provides that the Conference of the Parties serving as the meeting of the Parties to this Protocol shall, at its first meeting, adopt a process with respect to the appropriate elaboration of international rules and procedures in the field of liability and redress for damage resulting from transboundary movements of living modified organisms, analysing and taking due account of the ongoing processes in international law on these matters, and shall endeavour to complete this process within four years.
- ¹⁵ See Asian Biotechnology and Development Review (Vol. 7 No. 3) for details.
- ¹⁶ *See, e.g.*, Protocol on Liability and Compensation for Damage resulting from Transboundary Movements of Hazardous Wastes and their Disposal, Basel, 10 December 1999, UN doc. UNEP/CHW.5/29, Annex III (1999), Convention on Civil Liability for Nuclear Damage, Vienna, 21 May 1963 as amended by the Protocol of 12 September 1997 and International Convention on the Establishment of an International Fund for Compensation for Oil Pollution Damage, London, 27 November 1992.
- ¹⁷ UNEP/CBD/ICCP/3/INF/1.
- ¹⁸ Swiss Federal Research Station for Agroecology and Agriculture (<http://www.reckenholz.ch>).
- ¹⁹ Chaturvedi (2004).
- ²⁰ Damodaran (2005).
- ²¹ Chaturvedi (2005).
- ²² Ahmed, (1993).
- ²³ Khetrpal (2005).
- ²⁴ Narain (2003).
- ²⁵ Narain (2003).
- ²⁶ For more information on the BCH check the website <https://bch.biodiv.org/>
- ²⁷ More information on country, regional and organizational initiatives on RARM are available in the UNEP Document UNEP/CBD/BS/COP-MOP/2/9 and UNEP/CBD/BS/COP-MOP/2/INF/2
- ²⁸ Hota (2004).
- ²⁹ Rao (2005).
- ³⁰ *Ibid*.

References

- Ahmed, Iftikhar. 1993. ‘Biotechnology a Hope or a Threat?’, The Macmillan Series of ILO Studies: London.
- Charnovitz, Steve. 2002. ‘The Supervision of Health and Biosafety Regulation by the World Trade Rules’, in Kevin P Gallagher and Jacob Werksman (eds), *The Earthscan Reader on International Trade and Sustainable Development*, Earthscan Publishing Ltd., London, pp. 266-280.
- Chaturvedi, Sachin. 2005. ‘Dynamics of Biotechnology Research and Industry in India: Statistics, Perspectives and Key Policy Issues’. *OECD STI Working Papers Series No. 6*. Directorate for Science, Technology and Industry.
- Chaturvedi, Sachin. 2004. ‘Biotechnology in South Asia: Issues, Concerns and Opportunities’. *RIS Discussion Paper No. 68*.

- Chaturvedi, Sachin. 2004. 'Biosafety Regulation: Need for Fine Balancing'. *Economic and Political Weekly*, August 14, p 3693
- Cullet, Philippe. 2005. 'Liability and Redress: International Trends and Domestic Policy Options'. A paper presented at the National Consultations on Cartagena Protocol on Biosafety: Issues before MoP 2 organised by Research and Information System for the Developing Countries, New Delhi, May 24.
- Damodaran, A. 2005. 'The WTO Agreement, Cartagena Protocol and Biosafety Regulations'. A paper presented at the National Consultations on Cartagena Protocol on Biosafety: Issues before MoP 2 organised by Research and Information System for the Developing Countries, New Delhi, May 24.
- Desai, Bharat. 1997. 'Regulating Trans boundary Movements of Hazardous Wastes'. *Indian Journal of International Law*, Vol. 37, pp 43-61.
- Eric, Neumayer. 2002. 'WTO Rules and Multilateral Environmental Agreements,' in Kevin P Gallagher and Jacob Werksman [eds], *The Earthscan Reader on International Trade and Sustainable Development*, Earthscan Publishing Ltd., London, pp. 138-165.
- Graham, J.D. 2002. 'The Role of Precaution in Risk Assessment and Management: An American's View'. Remarks made at the United States Mission to the European Union, Jan. 11-12.
- Hota, Manoranjan. 2004. 'Capacity Building in Biosafety'. Paper presented during the second conference on Biotechnology for Asian Development: Regional Cooperation for Ensuring Access and Capacity Building organized by Research and Information Systems for the Non-aligned and other Developing Countries, New Delhi, April 7-8.
- Khetrapal, R.K. 2005. Comments on Precautionary Principle and Compliance Mechanism: Exploring the Policy Spaces at the National Consultation on Cartagena Protocol on Biosafety: Issues before MoP 2, RIS, New Delhi, May 24.
- Narain, Prem. 2003. 'Presentation on Plant Quarantine Order, 2003'. Department of Agriculture and Cooperation, Government of India.
- OECD. 2002. 'Uncertainty and Precaution: Implications for Trade and Environment'. *Joint Working Party on Trade and Environment*, September, pp. 38-41.
- Rao, S. R. 2005. 'Cartagena Protocol: Identifying the Issues of Concern'. A Keynote Address delivered at the National Consultations on Cartagena Protocol on Biosafety: Issues before MoP 2, RIS, New Delhi, May 24.
- Tickner, J. and Nancy Myers. 2000. 'Precautionary Principle: Current Status & Implementation'. Lowell: Lowell Centre for Sustainable Production.
- Volker Lehmann. 2002. 'From Rio to Johannesburg and Beyond: Globalizing Precaution for Genetically Modified Organisms'. A report for the Heinrich Boll Foundation, Washington Office, New York, April. Quoted from Vanderzwaag, D [1999] *Journal of Environmental Law Practice* 8, 355, and Foster, K.R. *et al*, [2000] *Science and the precautionary principle*. *Science*, 288, 5468 pp 979-981.
- Wiener, Jonathan B. and Michael D. Rogers. 2002. 'Comprising Precaution in the United States & Europe'. *Journal of Risk Research*. Vol. 5 (4), pp. 317-349. Carfax Publishing.

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